

Official Action, restriction is required on the grounds that two distinct inventions are claimed.

As stated in the Official Action, these can be distinct inventions only if the process can be practiced by another materially different apparatus or by hand or the apparatus can be used to practice another materially different process (MPEP 806.05(e)). The Official Action also states that the apparatus claimed can be used to practice another and materially different process such as freezing and thawing plastics or other non-biopharmaceutical.

New claim 18 has been added and claim 1 has been canceled, wherein claim 18 recites a method for thawing a frozen biopharmaceutical solution. The method includes heating the biopharmaceutical solution when at least a portion of the biopharmaceutical solution is frozen. The biopharmaceutical solution is heated using a heating element coupled to a container which contains the biopharmaceutical solution. The method further includes inducing oscillatory motion to the biopharmaceutical solution to thaw the at least a portion of the biopharmaceutical solution which is frozen. The oscillatory motion is induced using an oscillatory driver adapted to be coupled to the biopharmaceutical solution. Thus, this process cannot be performed by a materially different apparatus. Particularly, the biopharmaceutical solution is heated using a heating element coupled to a container which contains the biopharmaceutical solution. Also, oscillatory motion is induced to the biopharmaceutical solution using an oscillatory driver. The container, oscillatory driver, and heating element are necessary for the method, and thus cannot be performed by a materially different apparatus. Therefore, applicant respectfully asserts that the apparatus of claims 12-17 is necessary to execute the process of claims 2-11 and 18.

Further, it is not clear what other processes might be performed by the device, since the container thereof is configured to contain the biopharmaceutical solution, the heating element is coupled to the container for providing heat flux into the container, and the oscillatory driver is adapted to be coupled to a biopharmaceutical solution for inducing oscillatory motion thereto. Specifically, it is not clear how this apparatus could be used to freeze or thaw plastics, as

suggested in the Office Action. Accordingly, it is respectfully requested that the restriction requirement be withdrawn and each of claims 2-18 presently pending in this application be examined.

Additionally, in order for a restriction to be proper, the search of the claims together must be a severe burden on the Office (MPEP § 803). In this case, the process in claims 2-11 and 18 and apparatus for its practice in claims 12-17 are intertwined such that the process could not be practiced without the apparatus and the apparatus could not be used to practice any other process. It would necessarily follow that a search of prior art for both the process and apparatus would involve the same material. Thus, a search and examination of claims 2-18 on the merits will not create a serious burden to the Office, and Applicant respectfully requests the Examiner withdraw the restriction requirement.

### **Election of Species**

Regarding the requirement for an election of Species. The applicant hereby elects the species of FIG. 1, with traverse. Claims 2, 3, 6, 7, 8, 9, 12, 13, 15, 16 and 18 are believed to read on the ~~elected~~ species of FIG. 1. Moreover, independent claims 12 and 18 are clearly generic to the elected species. Applicant acknowledges that upon allowance of any of the generic claims, all claims dependent thereon will also be considered, regardless of whether such dependent claims read upon the elected species.

Regarding the requirement to elect a species, the election of species is proper when claims restricted to different species recite mutually exclusive characteristics of such different species. (MPEP 806.04(f)). In the instant case, there are no mutually exclusive characteristics which relate to different claims of the present application, which might conform to different species thereof. Thus, it is respectfully submitted that the requirement to elect a species is improper.

The Office Communication also requires that a complete listing of co-pending applications and/or prior art patents be submitted therein. Related to U.S. Patent No. 6,196,296 to Wisniewski is pending U.S. Application Serial No. 09/881,909, filed June 15, 2001, and published PCT Application No. PCT/US98/02065, now International Application No. WO/98/34078. Also, it is requested that the paper by L. Quan et al., referenced on page 4 of the specification be submitted. An information disclosure citation which recites the Quan reference and the PCT application is submitted herewith. The PCT application is also submitted herewith, while the Quan article will be submitted under separate cover, because applicant is currently attempting to obtain a copy of this article.

Attached hereto is a marked up version of the changes made to claims 2-6 and 9-11. New claim 18 has not been duplicated. The attached page is captioned "**Version with markings to show changes made.**"

If a telephone conference would be of assistance in advancing prosecution of the subject application, Applicants' undersigned attorney invites the Examiner to telephone him/her at the number provided.

Respectfully submitted,



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**"VERSION WITH MARKINGS TO SHOW CHANGES MADE"**

2.     *(Amended)*    The method of claim 18 [1], wherein the oscillatory motion of the oscillatory driver is harmonic motion.
  
3.     *(Amended)*    The method of claim 18 [1], wherein the oscillatory motion of the oscillatory driver is disharmonic motion.
  
4.     *(Amended)*    The method of claim 18 [1], wherein an amplitude of the oscillatory motion of the oscillatory driver ranges [from about] from about 0.0002 mm to about 10,000 mm.
  
5.     *(Amended)*    The method of claim 2, wherein an amplitude of the oscillatory motion of the oscillatory driver ranges from [about more preferably from] about 0.015 mm to about 350 mm.
  
6.     *(Amended)*    The method of claim 18 [1], wherein a frequency of the oscillatory motion of the oscillatory driver ranges from about 0.01 Hz to about 20 GHz.
  
9.     *(Amended)*    The method of claim 18 [1], wherein the oscillatory motion of the oscillatory driver is induced by inducing oscillatory motion of the container.
  
10.    *(Amended)*    The method of claim 18 [1], wherein the oscillatory motion of the oscillatory driver is induced by inducing oscillatory motion of the portion of the biopharmaceutical solution that is frozen.
  
11.    *(Amended)*    The method of claim 18 [1], wherein the oscillatory motion of the oscillatory driver is induced by inducing oscillatory motion of an unfrozen portion of the biopharmaceutical solution.